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PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/812,380

Filing Date: March 29, 2004

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Applicant: Iftikhar Khan , Nazir Khan

Group Art Unit: 3761

Examiner: Leslie R. Deak

Title: HYBRID ARTERIOVENOUS SHUNT

Attorney Docket: 1800-000001

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Declaration in Support of Application

1. We are the applicants in the above identified patent application

2. We declare the HERO™ (Hemodialysis Reliable Outflow) vascular access device, manufactured by Hemisphere Inc. company is a hemodialysis arteriovenous shunt identical to the applicants claimed invention. Clinical studies revealed new and unexpected results.

These results are a marked decrease in bacteremia rate versus currently used cuffed tunneled dialysis catheters and current arteriovenous graft literature.

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Improved adequacy of dialysis and patency versus currently used cuffed tunneled dialysis catheters.

Please see Exhibit 1 and Exhibit 2 as supporting documents for the HERO^{Tm} device.

In patients with central venous occlusion, the HERO^{Tm} device has achieved a success rate for allowing dialysis in patients with no other option, 96.2% of the time (50/52 patients).

3. I declare that all of the statements made herein of my knowledge are true and that all statements made upon information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment , or both, under Section 1001 of Title 18 of United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issuing therefrom.

Respectfully,

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Katzman, H. HeRO Vascular Access Device: A New Long-Term Dialysis Access Option for Access-Challenged Patients SCVS March 2008	**Objective:** The purpose of the study was to assess HeRO bacteremia and patency rates, adequacy of dialysis, and adverse events in graft-eligible and in "access challenged" subjects i.e., catheter dependent /poor-venous outflow subjects. **Methods:** The HeRO device consists of a 6 mm inner diameter (ID) ePTFE upper arm graft fitted with a titanium connector that is surgically coupled to a subcutaneous 5 mm ID nitinol reinforced silicone outflow catheter designed to bypass peripheral stenosis and exit into the right atrium via the IJ vein. Ninety HeRO subjects were enrolled in two study arms – access challenged (catheter arm) and graft-eligible (graft arm) subjects. Study endpoints included bacteremia and patency rates, adequacy of dialysis and adverse events. All results were compared to literature. **Results:** The data shows a marked decrease in the HeRO-related bacteremia rate in both study arms. The catheter arm HeRO-related bacteremia rate was 0.12/1,000 days versus IJ tunneled dialysis catheter (TDC) literature rate of 2.3/1,000 days. The graft arm HeRO-related bacteremia rate was 0.08/1,000 days versus graft literature rate of 0.11/1,000 days. HeRO patency rates (primary, primary-assisted, secondary and functional) in both study arms were better than TDC literature and equivalent to graft literature. HeRO adequacy of dialysis data (Kt/V 1.6-1.7) surpasses TDC literature (Kt/V 1.29-1.46) and was comparable to graft literature (Kt/V 1.37-1.67). Serious device/procedure-related adverse events were comparable to both TDC and graft literature. **Conclusions:** The HeRO device may be the best long-term access alternative for access challenged patients including those that are catheter dependent, are failing fistulas and grafts due to venous obstructions, have poor anatomy for a fistula or graft, or are receiving inadequate dialysis via a TDC.
Work, J. New Vascular Access Device Option for Catheter Dependent Patients ASDIN February 2008	**Purpose:** The purpose of this study was to evaluate catheter-dependent patients dialyzing with a new long-term access option, the Hemodialysis Reliable Outflow (HeRO™) vascular access device for device/implant procedure-related bacteremias compared to chronic tunneled dialysis catheter literature rates. HeRO is entirely subcutaneous and consists of a 6 mm inner diameter ePTFE upper arm graft connected to a 5 mm inner diameter nitinol-reinforced silicone outflow catheter that empties into the central venous system eliminating the need for graft to vein anastomosis, thus bypassing peripheral venous stenosis. **Methods:** This was a multi-center FDA regulated study designed on the premise that subjects considered catheter-dependent or poor candidates for fistula or graft due to inadequate venous outflow would experience a significant reduction in bacteremia rates with the HeRO device compared to a tunneled dialysis catheter. **Results:** The 36 subjects enrolled had on average 4.2 previous TDCs (range 1-16) and 1.7 previous bacteremias (range 1-4). As of 10/25/07, 8,450 HeRO days have accumulated with an average of 7.3 months of HeRO follow-up. The overall HeRO device/procedure-related bacteremia rate was 0.83/1,000 days compared to the catheter literature

10:15 am - 11:00 am

SCIENTIFIC SESSION 4 – DIALYSIS

Moderated by: Joann M. Lohr, MD & Anil Hingorani, MD

Learning Objectives:
- Describe recent trends in outcomes for arteriovenous access procedures
- Recognize evolving strategies to improve treatment planning for arteriovenous access procedures
- Identify novel strategies to enhance outcomes for arteriovenous access procedures in patients with challenging venous anatomy

MP14. Hemoaccess Placement in patients with Challenging Central Vein Occlusion
Chris Stout, MD, Jean Panneton, MD, Marc H. Glickman, MD. Eastern Virginia Medical, Norfolk, VA, USA.

December 12, 2008

Hemoaccess Placement in patients with Challenging Central Vein Occlusion

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***Chris Stout, MD**, Marc H. Glickman, md, Jean Panneton, MD.*
Eastern Virginia Medical, Norfolk, VA, USA.

OBJECTIVES: The placement of hemoaccess devices in patients with central vein occlusion is becoming more challenging for surgeons. The incidence of catheter dependent patients on dialysis continues to rise. Catheter dependent dialysis is fraught with complications including higher morbidity and mortality when compared to conventional dialysis. The purpose of the abstract is to present experience with the HeRO access device, which returns the patient to a conventional graft like access.

METHODS: The HeRO device, a graft with a central outflow component designed to bypass central venous stenosis, consists of ePTFE upper arm graft fitted with a titanium connector that is surgically coupled to a subcutaneous nitinol silicone outflow component which exits into the central venous system. Prospective data included average number of prior access procedures, the degree and type of central vein occlusion, vessel anatomy and surgical implant location.

RESULTS: Fifty two patients have undergone attempted placement of the HeRO devic. Forty patients have had placement of the device after successful angioplasty of near central vein occlusion, four patients have had placement of the device within the subclavian veins with central vein angioplasty, one patient had placement of the device into the SVC through

a retroperitoneal approach for SVC and IVC occlusion, two patients had placement into large azygous veins, four patients had placement through recannalized central veins and internal jugular veins and two patients had unsuccessful placement attempts due to inability to recannalilze the central veins. Fifty patients have had successful placement of this device and of these forty-eight patients have had successful conversion from catheter dependent dialysis to conventional dialysis

CONCLUSIONS: HeRO is the first AV access device to offer significant alternative to patients who are catheter dependent for their dialysis due to central vein pathology. These are very complex and demanding patients. HeRo device offers a promising alternative for these patients allowing conventional dialysis to be achieved

Tuesday, March 17